

11-07-03 1655
Image
Attorney Docket No. 9310.22CX

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Goudsmit et al.

Application Serial No: 09/463,352

Group Art Unit: 1655

Filed: January 21, 2000

Examiner: B. Sisson

For: *NUCLEIC ACID SEQUENCES THAT CAN BE USED AS PRIMERS AND PROBES IN THE AMPLICATION AND DETECTION OF ALL SUBTYPES OF HIV-1*

November 6, 2003

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMUNICATION FORWARDING SIGNED DECLARATION UNDER 37 C.F.R. § 1.131 TO REPLACE UNSIGNED DECLARATION SUBMITTED WITH SEPTEMBER 17, 2003 RESPONSE

Sir:

Enclosed is an executed DECLARATION OF JAAP GOUDSMIT, PIETER OUDSHOORN, SUZANNE JURRIAANS AND VLADIMIR VLADIMIROVICH LUKASHOV UNDER 37 C.F.R. § 1.131 submitted to replace the unsigned version of the Declaration as filed with the Response filed September 17, 2003 to address the rejections raised in the December 18, 2002 Office Action issued regarding the above-referenced patent application. Entry and consideration of the enclosed Declaration is respectfully requested.

Respectfully submitted,

Mary L. Miller

Mary L. Miller

Registration No. 39,303

Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401
Customer Number 20792

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number: EV 353611033 US

Date of Deposit: November 6, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Cathy A. Schetzina
Cathy A. Schetzina



Attorney Docket No. 9310.22CX

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Goudsmit et al.

Application Serial No: 09/463,352

Group Art Unit: 1655

Filed: January 21, 2000

Examiner: B. Sisson

For: *NUCLEIC ACID SEQUENCES THAT CAN BE USED AS PRIMERS AND PROBES IN
THE AMPLICATION AND DETECTION OF ALL SUBTYPES OF HIV-1*

MAIL STOP RCE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION OF JAAP GOUDSMIT,
PIETER OUDSHOORN, SUZANNE JURRIAANS
AND VLADIMIR VLADIMIROVICH LUKASHOV
UNDER 37 C.F.R. § 1.131**

Sir:

We, Jaap Goudsmit, Pieter Oudshoorn, Suzanne Jurriaans and Vladimir Vladimirovich Lukashov hereby declare that:

1. We are the inventors of the subject matter of the rejected claims pending in the above-referenced patent application.
2. Prior to June 25, 1997, we conceived and reduced to practice the oligonucleotides having the nucleotide sequence of SEQ ID NOs 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11, respectively, as recited in the pending claims, as well as methods of use and kits employing these oligonucleotides to detect HIV-1 nucleic acid in a sample
3. In support of the above statement, we hereby submit as Appendix A a copy of relevant pages of an internal memorandum entitled "Feasability of a qualitative NASBA assay with a broad HIV-1 clade reactivity" prepared by non-inventor, F. Jacobs, under the direction of

group leader and inventor, Pieter Oudshoorn, and submitted to Akzo Nobel. The dates within this document have been blocked out, but are before June 25, 1997.

Specifically, this memorandum shows, in relevant part, with irrelevant text blocked out, on page 4 under section 2.1 entitled "Design of primers and probes," a listing of oligonucleotides identified as P1.1, P1.2, U5 end, P2.1, P2.2, HIV-1 LTR-bio, HIV-LTR-AMN1 and HIV-LTR-AMN2. These oligonucleotides are the oligonucleotides identified in the specification and pending claims as SEQ ID NO:1 and SEQ ID NO:9, SEQ ID NO:2 and SEQ ID NO:10, SEQ ID NO:3 and SEQ ID NO:12, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 and SEQ ID NO:8, respectively. The oligonucleotides identified as SEQ ID NOs 1, 2 and 3 are the same as the oligonucleotides identified as SEQ ID NOs 9, 10 and 11, respectively, with the distinction that the latter three oligonucleotides are operably linked to a promoter sequence. (See page 7, lines 13-15 of the specification: "SEQ ID NO 9-11 actually comprise the sequence as reflected by SEQ ID 1-3. In SEQ ID 9-11, the sequences of SEQ ID 1-3 are operably linked to a promoter sequence (the T7 promoter sequence). This makes the sequences especially suitable for use as upstream primer in a transcription based amplification technique such as NASBA.")

The memorandum also shows, in relevant part, with irrelevant text blocked out, on page 5 under section 2.2, entitled "Evaluation and optimization of the primers and probes," a description of a protocol for detecting HIV nucleic acid using the oligonucleotides of this invention. Results obtained by conducting this protocol are shown, in relevant part, with irrelevant text blocked out, on page 10, under section 3.2, entitled "Evaluation of selected primers."

6. In summary, our statements herein and the documents concurrently submitted show conception and reduction to practice of the claimed invention prior to June 25, 1997.

7. We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true. We further declare that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jaap Goudsmit
Jaap Goudsmit

October 3, 2003
Date

Pieter Oudshoorn

Date

Suzanne Jurriaans

Date

Vladimir Vladimirovich Lukashov

Date



Attorney Docket No. 9310.22CX

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Goudsmit et al.

Application Serial No: 09/463,352

Group Art Unit: 1655

Filed: January 21, 2000

Examiner: B. Sisson

For: *NUCLEIC ACID SEQUENCES THAT CAN BE USED AS PRIMERS AND PROBES IN THE AMPLICATION AND DETECTION OF ALL SUBTYPES OF HIV-1*

MAIL STOP RCE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION OF JAAP GOUDSMIT,
PIETER OUDSHOORN, SUZANNE JURRIAANS
AND VLADIMIR VLADIMIROVICH LUKASHOV
UNDER 37 C.F.R. § 1.131**

Sir:

We, Jaap Goudsmit, Pieter Oudshoorn, Suzanne Jurriaans and Vladimir Vladimirovich Lukashov hereby declare that:

1. We are the inventors of the subject matter of the rejected claims pending in the above-referenced patent application.
2. Prior to June 25, 1997, we conceived and reduced to practice the oligonucleotides having the nucleotide sequence of SEQ ID NOs 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11, respectively, as recited in the pending claims, as well as methods of use and kits employing these oligonucleotides to detect HIV-1 nucleic acid in a sample
3. In support of the above statement, we hereby submit as Appendix A a copy of relevant pages of an internal memorandum entitled "Feasability of a qualitative NASBA assay with a broad HIV-1 clade reactivity" prepared by non-inventor, F. Jacobs, under the direction of

group leader and inventor, Pieter Oudshoorn, and submitted to Akzo Nobel. The dates within this document have been blocked out, but are before June 25, 1997.

Specifically, this memorandum shows, in relevant part, with irrelevant text blocked out, on page 4 under section 2.1 entitled "Design of primers and probes," a listing of oligonucleotides identified as P1.1, P1.2, U5 end, P2.1, P2.2, HIV-1 LTR-bio, HIV-LTR-AMN1 and HIV-LTR-AMN2. These oligonucleotides are the oligonucleotides identified in the specification and pending claims as SEQ ID NO:1 and SEQ ID NO:9, SEQ ID NO:2 and SEQ ID NO:10, SEQ ID NO: 3 and SEQ ID NO:12, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 and SEQ ID NO:8, respectively. The oligonucleotides identified as SEQ ID NOs.1, 2 and 3 are the same as the oligonucleotides identified as SEQ ID NOs 9, 10 and 11, respectively, with the distinction that the latter three oligonucleotides are operably linked to a promoter sequence. (See page 7, lines 13-15 of the specification: "SEQ ID NO 9-11 actually comprise the sequence as reflected by SEQ ID 1-3. In SEQ ID 9-11, the sequences of SEQ ID 1-3 are operably linked to a promoter sequence (the T7 promoter sequence). This makes the sequences especially suitable for use as upstream primer in a transcription based amplification technique such as NASBA.")

The memorandum also shows, in relevant part, with irrelevant text blocked out, on page 5 under section 2.2, entitled "Evaluation and optimization of the primers and probes," a description of a protocol for detecting HIV nucleic acid using the oligonucleotides of this invention. Results obtained by conducting this protocol are shown, in relevant part, with irrelevant text blocked out, on page 10, under section 3.2, entitled "Evaluation of selected primers."

6. In summary, our statements herein and the documents concurrently submitted show conception and reduction to practice of the claimed invention prior to June 25, 1997.

Attorney Docket No. 9310.22CX
Application Serial No. 09/463,352
Page 3 of 3

7. We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true. We further declare that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jaap Goudsmit



Pieter Oudshoorn

Date

Oct 1st 2003

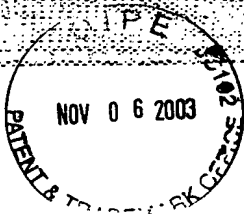
Date

Suzanne Jurriaans

Date

Vladimir Vladimirovich Lukashov

Date



Attorney Docket No. 9310.22CX

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Goudsmit et al.

Application Serial No: 09/463,352

Group Art Unit: 1655

Filed: January 21, 2000

Examiner: B. Sisson

For: *NUCLEIC ACID SEQUENCES THAT CAN BE USED AS PRIMERS AND PROBES IN
THE AMPLICATION AND DETECTION OF ALL SUBTYPES OF HIV-1*

MAIL STOP RCE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION OF JAAP GOUDSMIT,
PIETER OUDSHOORN, SUZANNE JURRIAANS
AND VLADIMIR VLADIMIROVICH LUKASHOV
UNDER 37 C.F.R. § 1.131**

Sir:

We, Jaap Goudsmit, Pieter Oudshoorn, Suzanne Jurriaans and Vladimir Vladimirovich Lukashov hereby declare that:

1. We are the inventors of the subject matter of the rejected claims pending in the above-referenced patent application.
2. Prior to June 25, 1997, we conceived and reduced to practice the oligonucleotides having the nucleotide sequence of SEQ ID NOs 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11, respectively, as recited in the pending claims, as well as methods of use and kits employing these oligonucleotides to detect HIV-1 nucleic acid in a sample
3. In support of the above statement, we hereby submit as Appendix A a copy of relevant pages of an internal memorandum entitled "Feasability of a qualitative NASBA assay with a broad HIV-1 clade reactivity" prepared by non-inventor, F. Jacobs, under the direction of

group leader and inventor, Pieter Oudshoorn, and submitted to Akzo Nobel. The dates within this document have been blocked out, but are before June 25, 1997.

Specifically, this memorandum shows, in relevant part, with irrelevant text blocked out, on page 4 under section 2.1 entitled "Design of primers and probes," a listing of oligonucleotides identified as P1.1, P1.2, U5 end, P2.1, P2.2, HIV-1 LTR-bio, HIV-LTR-AMN1 and HIV-LTR-AMN2. These oligonucleotides are the oligonucleotides identified in the specification and pending claims as SEQ ID NO:1 and SEQ ID NO:9, SEQ ID NO:2 and SEQ ID NO:10, SEQ ID NO: 3 and SEQ ID NO:12, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 and SEQ ID NO:8, respectively. The oligonucleotides identified as SEQ ID NOs 1, 2 and 3 are the same as the oligonucleotides identified as SEQ ID NOs 9, 10 and 11, respectively, with the distinction that the latter three oligonucleotides are operably linked to a promoter sequence. (See page 7, lines 13-15 of the specification: "SEQ ID NO 9-11 actually comprise the sequence as reflected by SEQ ID 1-3. In SEQ ID 9-11, the sequences of SEQ ID 1-3 are operably linked to a promoter sequence (the T7 promoter sequence). This makes the sequences especially suitable for use as upstream primer in a transcription based amplification technique such as NASBA.")

The memorandum also shows, in relevant part, with irrelevant text blocked out, on page 5 under section 2.2, entitled "Evaluation and optimization of the primers and probes," a description of a protocol for detecting HIV nucleic acid using the oligonucleotides of this invention. Results obtained by conducting this protocol are shown, in relevant part, with irrelevant text blocked out, on page 10, under section 3.2, entitled "Evaluation of selected primers."

6. In summary, our statements herein and the documents concurrently submitted show conception and reduction to practice of the claimed invention prior to June 25, 1997.

Attorney Docket No. 9310.22CX
Application Serial No. 09/463,352
Page 3 of 3

7. We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true. We further declare that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jaap Goudsmit

Date

Pieter Oudshoorn

Date

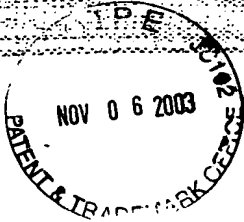
Suzanne J. Janssens

Date

30 Oct 2003

Vladimir Vladimirovich Lukashov

Date



Attorney Docket No. 9310.22CX

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Goudsmit et al.

Application Serial No: 09/463,352

Group Art Unit: 1655

Filed: January 21, 2000

Examiner: B. Sisson

For: *NUCLEIC ACID SEQUENCES THAT CAN BE USED AS PRIMERS AND PROBES IN THE AMPLICATION AND DETECTION OF ALL SUBTYPES OF HIV-1*

MAIL STOP RCE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

DECLARATION OF JAAP GOUDSMIT,
PIETER OUDSHOORN, SUZANNE JURRIAANS
AND VLADIMIR VLADIMIROVICH LUKASHOV
UNDER 37 C.F.R. § 1.131

Sir:

We, Jaap Goudsmit, Pieter Oudshoorn, Suzanne Jurriaans and Vladimir Vladimirovich Lukashov hereby declare that:

1. We are the inventors of the subject matter of the rejected claims pending in the above-referenced patent application.
2. Prior to June 25, 1997, we conceived and reduced to practice the oligonucleotides having the nucleotide sequence of SEQ ID NOs 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11, respectively, as recited in the pending claims, as well as methods of use and kits employing these oligonucleotides to detect HIV-1 nucleic acid in a sample
3. In support of the above statement, we hereby submit as Appendix A a copy of relevant pages of an internal memorandum entitled "Feasability of a qualitative NASBA assay with a broad HIV-1 clade reactivity" prepared by non-inventor, F. Jacobs, under the direction of

group leader and inventor, Pieter Oudshoorn, and submitted to Akzo Nobel. The dates within this document have been blocked out, but are before June 25, 1997.

Specifically, this memorandum shows, in relevant part, with irrelevant text blocked out, on page 4 under section 2.1 entitled "Design of primers and probes," a listing of oligonucleotides identified as P1.1, P1.2, U5 end, P2.1, P2.2, HIV-1 LTR-bio, HIV-LTR-AMN1 and HIV-LTR-AMN2. These oligonucleotides are the oligonucleotides identified in the specification and pending claims as SEQ ID NO:1 and SEQ ID NO:9, SEQ ID NO:2 and SEQ ID NO:10, SEQ ID NO:3 and SEQ ID NO:12, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 and SEQ ID NO:8, respectively. The oligonucleotides identified as SEQ ID NOs 1, 2 and 3 are the same as the oligonucleotides identified as SEQ ID NOs 9, 10 and 11, respectively, with the distinction that the latter three oligonucleotides are operably linked to a promoter sequence. (See page 7, lines 13-15 of the specification: "SEQ ID NO 9-11 actually comprise the sequence as reflected by SEQ ID 1-3. In SEQ ID 9-11, the sequences of SEQ ID 1-3 are operably linked to a promoter sequence (the T7 promoter sequence). This makes the sequences especially suitable for use as upstream primer in a transcription based amplification technique such as NASBA.")

The memorandum also shows, in relevant part, with irrelevant text blocked out, on page 5 under section 2.2, entitled "Evaluation and optimization of the primers and probes," a description of a protocol for detecting HIV nucleic acid using the oligonucleotides of this invention. Results obtained by conducting this protocol are shown, in relevant part, with irrelevant text blocked out, on page 10, under section 3.2, entitled "Evaluation of selected primers."

6. In summary, our statements herein and the documents concurrently submitted show conception and reduction to practice of the claimed invention prior to June 25, 1997.

7. We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true. We further declare that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jaap Goudsmit

Date

Pieter Oudshoorn

Date

Suzanne Jurriaans

Date

Vladimir Vladimirovich Lukashov

Date

Oktober 6, 2003